



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Cincinnati District Office  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2772

**WARNING LETTER**

Cin WL -6187-0  
January 29, 2001

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Bradley A. Blackburn, M.D.  
Medical Director  
MSN Imaging Center  
4330 West 150<sup>th</sup> St.  
Cleveland, OH 44135

Facility I.D.#: 223718

Dear Dr. Blackburn:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on January 17, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

**Quality Assurance – Equipment - 21 CFR 900.12(e)(1)(i)-(iii)**

- a. Your records revealed that your facility processed mammograms when the processor quality control parameters were out of limits for eight days.
- b. Your records showed that your facility processed mammograms when the processor quality control records were missing 16 of 16 days or 100% of total days of operation in May 2000.

**Quality Assurance – Equipment - 21 CFR 900.12(e)(2)(i)-(iv)**

Your records revealed that your facility phantom quality control records for the mammography unit were missing at least twelve (12) weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the consecutive weeks of April 7 to June 30, 2000.

## **Medical Records and Mammography Reports - 21 CFR 900.12(c)(2)**

Your standard operating procedures are inadequate for your facility in communicating to the patients the results of their mammograms. Your standard operating procedures fail to state that all of the mammography results will be communicated to each of the patients in a lay summary report within 30 days of the mammography examinations.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 noncompliance item that was listed on the inspection report provided to you at the close of the inspection. This Level 2 noncompliance item is:

### **Medical Records and Mammography Reports - 21 CFR 900.12 (c)(1)(iv)(A)-(E) &(v)**

Three of five random interpreting physician mammography reports did not contain the required overall final assessment of findings.

The other item listed in your January 17, 2001 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

You must act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen  
MQSA Compliance Officer  
Food & Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
FAX: 513-679-2772


Also, please send a copy to the State radiation control office:

Ms. Terri Eckert  
Ohio Department of Health  
Radiologic Technology Section  
161 South High St., Suite 400  
Akron, OH 44308

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

  
Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
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